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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,509

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Christelle Marie Guittet

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EXAMINER

SIMS, JASON M

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

07/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,509	Applicant(s) GUITTET ET AL.	
	Examiner JASON M. SIMS	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-11 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-11, and 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments, filed 4/30/2009, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 4/30/2009, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claims 1-5, 7-11, and 13-17 are the current claims hereby under examination.

Claim Rejections - 35 USC § 101

Response to Arguments

Applicant's arguments, filed 4/30/2009, with respect to the rejection of claims under 35 USC 101 have been fully considered and are persuasive because of applicant's amendments and arguments. Therefore the rejection has been withdrawn.

Claim Rejections - 35 USC § 112

Response to Arguments

Applicant's arguments, filed 4/30/2009, with respect to the rejection of claims under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicant's amendments and arguments. Therefore the rejection has been withdrawn.

Claim Rejections - 35 USC § 102-Maintained

Art Unit: 1631

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 7, 9-11, 13, and 15-17 rejected under 35 U.S.C. 102(b) as being anticipated over Cheng et al. (Submitted on IDS filed 7/25/2005).

The claims are drawn to a method of grading tubules in a first image of a histological slide, the method having the steps of:

- a) providing a second image of first objects in the first image which are sufficiently large and have pixel values at boundaries indicating epithelial layers and potential tubules,
- b) providing a third image of second objects in the first image having pixel values not indicating epithelial layers, but instead fat and holes within tubules,
- c) combining data from the second and third images to identify as holes within tubules those selected second objects which are within first objects,
- d) performing one or more of the following:
 - i) counting first objects in the first image which may potentially be tubules to provide a parameter NOB,
 - ii) counting the first objects having selected second objects within them and likely to be tubules to provide a parameter N,

- iii) determining the relative areas of selected second objects as proportions of respective first objects within which they are located to provide parameters $RATIO$,
 - iv) determining the total area of selected second objects as a proportion of total area of first objects within which they are located to provide a parameter $SURF$,
 - v) determining a parameter $PERCENT = N/NOB$, and
 - vi) counting the number of first objects containing at least medium sized holes to provide a parameter T , and
- e) grading the first image's tubules on the basis of the one or more parameters as aforesaid with reference to parameter threshold values.

Cheng et al. at the abstract teach a method of grading tubules in digitized images of microscopic slides, which reads on the preamble of the instantly claimed method. Cheng et al. at page 323, part B. teach identifying pixel value characteristics that potentially may be tubules wherein the pixel values are homogeneously bright surround by dark boundaries (i.e. epithelial layers, as applicant has stated in paragraph [0083] of their published application a tubule "appears as a white area surrounded by a dark epithelial layer (or boundary)"), which reads on part a). Cheng et al. at page 323, step C. and page 324 teach a method of making a third image wherein each of the first identified potential tubules, i.e. objects, are further analyzed to identify pixel values of likely tubules, which reads on steps b) and c). Cheng et al. reads on step b) because the pixel values, which indicate a potential tubule are also pixel values characteristic of

Art Unit: 1631

fat and holes, i.e. rough textures. For example, Cheng et al. at page 324, last paragraph states that tubules and rough textures, both comprise homogeneous areas, wherein the pixel values of the homogeneous areas of tubules reads on the broad and reasonable interpretation of pixel value characteristics of fat and holes, which are comprised of similar homogeneous areas. Furthermore, the analysis taught by Cheng et al. step C, is performed on the initial first objects wherein the first objects are potential or likely tubules and whose pixel values are characteristic of fat and holes. Cheng et al. at page 326, step D, teach a method of counting the tubule areas and using the counting to obtain a score for physicians, which reads on step d), substep ii), step e), and step f). With regards to claims 7 and 13 directed to an apparatus and instructions, i.e. program, Cheng et al. teach a computer system for implementing the algorithms, wherein the computer executing the algorithms inherently comprises the instructions on a computer readable medium at pages 327 and 328.

Cheng et al. at pages 323-328 teach wherein bright area pixels have different binary values than darker areas as in claims 3, 9, and 15.

Cheng et al. teach claims 4, 10, and 16 at page 328.

Cheng et al. at page 326, step D., teach grading tubules comparable with that of a physician, i.e. medical expert as claims 5, 11, and 17.

Response to Arguments

Applicant's arguments filed 4/30/2009 have been fully considered but they are not persuasive.

Applicant argues that Cheng's successive stages in processing an image differs from the claimed inventive steps of providing a second image and third image and combining the data as in steps a) - c).

Applicant's arguments are not found persuasive because a broad and reasonable interpretation of steps a)- c) does not exclude a successive image processing method that produces second and third images built from the first image from reading on the limitations of providing a second and third image and combining their data as in steps a) – c). Therefore, the successive image processing which generates a second and third image wherein the generation is combining the data from each of the previously generated data reads on the broad and reasonable interpretation of steps a) - c).

Applicant further argues important technical advantages of the instant invention and Cheng, such as a tubule can appear round, oval, cylindrical, or irregular depending on the angle of the section to the duct axis and the shape of the duct after sectioning. Applicant argues that their invention is workable with normal histopathology tubule specimens which may have variable and possibly irregular tubule shapes, whereas Cheng cannot.

Applicant's arguments are not found persuasive because they are not commensurate in scope with the claimed invention.

Applicant further argues that Cheng cannot compensate a tubule count for tubules having more than one hole unlike applicant's invention.

Applicant's arguments are not found persuasive because they are not commensurate in scope with the claimed invention.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/ Jason Sims /

/Michael Borin/
Primary Examiner, Art Unit 1631